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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

12/10/2004

Brian R Morrill Esq
Biomeasure Incorporated
27 Maple Street
Milford, MA 01757-3650

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/10/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,692	07/15/2002	Thomas Ciaran Loughman	50165/013001	4672

TITLE OF INVENTION: PROCESS TO MAKE A SUSTAINED RELEASE FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$0	\$1400	03/10/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(703) 746-4000**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

7590 12/10/2004
Brian R Morrill Esq
Biomeasure Incorporated
27 Maple Street
Milford, MA 01757-3650

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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10/049,692	07/15/2002	Thomas Ciaran Loughman	50165/013001	4672

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nonprovisional	NO	\$1400	\$0	\$1400	03/10/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
FUBARA, BLESSING M	1615	424-40000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). <input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. <input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, _____ (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. _____ _____
---	---

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY and STATE OR COUNTRY) _____

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed: <input type="checkbox"/> Issue Fee <input type="checkbox"/> Publication Fee (No small entity discount permitted) <input type="checkbox"/> Advance Order - # of Copies _____	4b. Payment of Fee(s): <input type="checkbox"/> A check in the amount of the fee(s) is enclosed. <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. <input type="checkbox"/> The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).
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5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____	Date _____
Typed or printed name _____	Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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DATE MAILED: 12/10/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 452 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 452 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability

Application No.

10/049,692

Examiner

Blessing M. Fubara

Applicant(s)

LOUGHMAN, THOMAS CIARAN

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication of 07/15/02.
2. ☒ The allowed claim(s) is/are 1-7.
3. ☒ The drawings filed on 15 July 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 5/17/02, 6/20/02, 9/21/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of request of change of correspondence address and associate power of attorney filed 07/19/04; preliminary amendment filed 07/15/02; IDS filed 09/21/04, 06/20/02 and 0/17/02.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In set⁺ the abstract provided on a separate sheet of paper.

Allowable Subject Matter

1. The following is an examiner's statement of reasons for allowance:

Kim et al. (US 5,552,520, cited in applicants specification) discloses the synthesis of BIM-23190 Somatostatin agonist (column 19, lines 20-30), which is compound A of the instant claims. Kim differs from the instant claims in that Kim does not disclose reacting BIM-23190, the somatostatin agonist with a polymer that comprises lactide, glycolide and tartaric acid units where compound A (BIM 23190) ionically bonds to the polymer.

Shalaby et al. (US 5,672,659) discloses a composition that comprises polyester that is ionically conjugated to a bioactive polypeptide (abstract). The polyester is a member selected from the group consisting of L-lactic acid, D-lactic acid, DL-lactic acid, ϵ -caprolactone, p-dioxanone, ϵ -caproic acid, substituted and unsubstituted trimethylene carbonate, 1,5-dioxepan-2-one, 1,4-dioxepan-2-one, glycolide, glycolic acid, L-lactide, D-lactide, DL-lactide, meso-lactide,

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alkylene oxalate, cycloalkylene oxalate, alkylene succinate, (β -hydroxybutyrate), and optically active isomers, racemates or copolymers of any of the above (column 1, line 55 to column 2, line 10). In Shalaby, the polyester is partially acid tipped with glutaric anhydride (column 2, lines 13-15). Somatostatin is one of the bioactive polypeptides that can ionically bond to the polyester and BIM-21003 is a somatostatin that is conjugated to d,l-lactide/glycolide/citric acid (column 2, line 29; column 12, lines 5-23) and in example 9, somatostatin tumor inhibiting analogue, BIM-23014 is conjugated to lactic/glycolide/malic copolymer. Shalaby differs from the instant claims in that Shalaby does not disclose a copolymer that contains tartaric acid; Shalaby does not also disclose the specific somatostatin derivative, BIM-23190; also, Shalaby does not disclose the ratio of glycolide to lactide that is recited by the instant claims; and Shalaby does not disclose the process of instant claim 1.

Culler et al. (US 6,268,342) discloses a composition that comprises somatostatin agonist, which has the structure of compound A of the instant claim (column 6, lines 35-45) and sustained release polymer such as lactic acid polymer or lactic-glycolic acid copolymer (column 10, lines 59-67). Culler differs from the instant claims in that Culler does not disclose that the polyester is ionically bonded to the somatostatin; Culler does not disclose that the polyester is tipped with tartaric acid and Culler does not teach the process of forming polyester-somatostatin ionic conjugate of the type recited in the instant claims.

Melmed et al. (US 5,972,893) discloses a method of treating hyperprolactinemia with a composition that contains somatostatin agonist (column 5, line 49) such as BIM-23190 (Examples 8 and 9) and when the composition is administered as a sustained release implant, the composition comprises lactic acid polymer or lactic acid co-glycolic acid copolymer (column 6, lines 51-60).

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Melmed differs from the instant claims in that Melmed does not disclose ionic conjugate of the somatostatin and the polyester; also the polymer of Melmed is not end tipped with tartaric acid.


The pending claims are thus allowable.

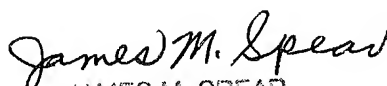
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
Patent Examiner
Tech. Center 1600


JAMES M. SPEAR
PRIMARY EXAMINER
AU 16 15

Art Unit: 1615

ABSTRACT OF THE DISCLOSURE

This invention pertains to a process for making a sustained release complex. Compound (I), which comprises Compound (A), having formula (A), and a copolymer comprising poly (l)-lactic-glycolic-tartaric acid (P (I) LGT), wherein the amino group of Compound (A) is ionically bound to a carboxyl group of the (P (I) LGT).

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
A4 16 15

Notice of References Cited

Application/Control No.

10/049,692

Applicant(s)/Patent Under
Reexamination
LOUGHMAN, THOMAS CIARAN

Examiner

Blessing M. Fubara

Art Unit

1615

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,552,520	09-1996	Kim et al.	530/311
	B	US-5,863,985	01-1999	Shalaby et al.	525/54.1
	C	US-6,268,342	07-2001	Culler et al.	514/12
	D	US-5,972,893	10-1999	Melmed et al.	514/16
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

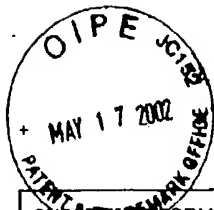
FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Sheet 1 of 1

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50165/013001
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Serial No.	10/049,692
		Applicant	Thomas Ciaran Loughman
		Filing Date	February 15, 2002
		Group	
(37 C.F.R. §1.98(b))		IDS Filed	May 13, 2002

U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
bf	WO 01/12233 A2	22.02.01	PST KIO	47	48	NO
bf	WO 97/39738	30.10.97	PST KIO	9	16	NO
bf	WO 94/15587	21.7.94	PST KIO	9	16	no
bf	WO 95/04752	16.2.95	PST KIO	5	02	NO

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

EXAMINER <i>Blessing Eubara</i>	DATE CONSIDERED <i>12-2-04</i>
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

2002 3 2 1007

Sheet 1 of 1

SUBSTITUTE FORM PTO-1449 (MODIFIED) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. §1.98(b))	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Attorney Docket No.	50165/013001
			Serial No.	10/049,692
			Applicant	Thomas Ciaran Loughman
			Filing Date	February 15, 2002
			Group	
		IDS Filed	June 14, 2002	

U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
BF	WO 99/38535 A	05.08.99	PCT NO			
BF	WO 00/43435 A	27.7.00	PCT NO			

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

EXAMINER Blessing Fubra

DATE CONSIDERED

12-2-04

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
094/IE/PCT/USAPPLICATION NO.
~~10/049,962~~ 10/049,682INFORMATION DISCLOSURE CITATION
IN AN APPLICATIONAPPLICANT
LOUGHMAN, Thomas C.FILING DATE
July 15, 2002GROUP/EXAMINER
1615/Unknown

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
BF	BA	5552520	9-1996	Kim et al	530	311	9-1994

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
BF	BB	00/12232		PCT WO			
BF	BC	HUP0102373		Hungary			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER

Blessing Fubara

DATE CONSIDERED

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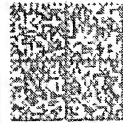
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